a penetrating element reciprocatably mounted in the lumen of the guide tube so that the penetrating element can be advanced from the distal end of the guide tube to penetrate a luminal wall in a direction determined by deflection of the distal end of the guide tube.

43. A device as in claim 42, wherein the guide tube has a pre-formed tip which deflects laterally as the guide tube is advanced from the catheter.

44. A device as in claim 42, wherein the penetrating element is a stylet.

45. A device as in any of claims 42 to 44, further comprising an expandable anchor disposed over at least a portion of the catheter. --

REMARKS

Claims 33-39 were examined, with claims 1-32, and 40-41, having been withdrawn pursuant to a Restriction Requirement. The claims have been amended and canceled and new claims added as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

Applicants confirm the telephone election of the claims of Group III (claims 33-39) without traverse. All non-elected claims have now been canceled without prejudice to refiling in a subsequent application.

Applicants note the objection to the drawings. The objection is overcome by canceling claim 39.

Claims 33-39 were objected to as being indefinite. In particular, the Examiner noted that there was no difference between the catheter and the support tube. While Applicants believe that there is a difference, for example as described in the specification at page 5, line 34, and page 8, lines 5-9, Applicants concede that the support tube is not illustrated in the drawings and have therefore canceled recitation of support tube in the claims. Thus, the rejection for indefiniteness has been overcome.

Claims 33-39 were rejected as being anticipated by U.S. Patent No. 5,387,193, to Miraki. Such rejection is respectfully traversed in part and overcome in part.

The Examiner argues that Miraki describes a catheter having "means advancable from the catheter (84) for creating a second access penetration and providing a filament path (84) between said first and second access penetrations; wherein . . . the advancable means is reciprocatable received in the catheter lumen (112); wherein the advancable means has a pre-formed tip which deflects laterally as it is advanced from the catheter (84) wherein the advancable means comprises a guide tube having a lumen therethrough (110) and a penetrating element removable received in the lumen and extending from the distal tip of the guide tube, wherein the penetrating means can be withdrawn from the guide tube after the guide tube has been placed between the access penetrations to leave the guide tube lumen as a filament path . . ." Applicants disagree.

Miraki '193 discloses a rapid exchange balloon angioplasty catheter. The element 84 referred to by the Examiner is not a catheter or an advancable means, nor does it provide a filament path. Element 84 is a tapered stiffening section which is attached at the distal end of a hypotube. (See, col. 4, lines 45-54.) The purpose of the hypotube/stiffening section is to stiffen the balloon catheter shaft in a region where the guidewire will not pass. The Examiner will appreciate that "over-the-wire" catheters, where guidewires are received through the entire length of the catheter, rely on the guidewire for stiffening. In rapid exchange designs, such as that described in the Miraki '193 patent, the guidewire extends only through a distal portion of the catheter, see Fig. 2, which illustrates the guidewire exiting at port 60. In such cases, the Miraki '193 patent suggests that a separate hypotube/tapered stiffening member be introduced into the catheter shaft in order to provide for stiffening. In the embodiments of Figs. 2-8, the hypotube is fixed and neither advancable nor removable from the catheter body. In the embodiment of Figs. 9 and 10, the hypotube is removable from the proximal end of the catheter, but not advancable beyond the distal end of the catheter.

With this more complete understanding of the teachings of Miraki '193, it can be seen that independent claim 33 is simply not anticipated or rendered obvious. Claim 33 specifically requires that the means for creating a second access penetration be **advancable** from the catheter. The tapered stiffening element of Miraki '193 is not intended to penetrate tissue and is not advancable from the catheter. Indeed, the hub structure of the catheter to which the hypotube is attached would prevent any attempt at advancing the stiffening element.

Moreover, there would be no reason to advance the stiffening element since its purpose is to provide a gradually tapered stiffening in the region of the guidewire port 60. Finally, any actual advancement of the stiffening element, should one figure out how to do so, would result in puncturing of the angioplasty balloon, hardly a desirable result.

For all these reasons, Applicants believe that independent claim 33, as well as the claims dependent thereon are clearly allowable over the cited art. Applicants have added new claims 42-45 which even further distinguish the teachings of Miraki '193. Claim 42 is specifically directed at an exemplary embodiment of the invention as shown in, e.g., Fig. 1 and Figs. 2A-2D. The positioning device comprises a catheter, a guide tube, and a penetrating element, with the guide tube being reciprocatably received in a lumen of the catheter and the penetrating element being reciprocatably received in a lumen of the guide tube. Such a structure is contrary to Miraki '193, which teaches a stiffening element 84 permanently affixed to a distal tip of a hypotube which is fixedly secured within the catheter body (except in the embodiment of Figs. 9 and 10 where it may be withdrawn from a proximal end of the catheter body, but not distally advanced).

For all these reasons, Applicants believe that all pending claims are in condition for allowance and request that the application be passed to issue at an early date.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at 650-326-2400.

Respectfully submitted,

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